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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,922	06/13/2001	Randall S. Hickie	82021-0012	2867

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,922

Applicant(s)

HICKLE ET AL

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-14, 16-66 and 80-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16-26, 28, 32-39, 41, 42, 44, 46-57, 60-66, 80-83, 87-97, 103-109, 114-120, 126 and 127 is/are rejected.
- 7) ☒ Claim(s) 10-14, 27, 29-31, 40, 43, 45, 58, 59, 84-86, 98-102, 110-113 and 121-125 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/05 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 10-14, 16-56, 64-66, 80-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Independent claim 1 recites the limitation "said two nostril portions" in line 10. There is insufficient antecedent basis for this limitation in the claim.

5. Independent claim 37 recites the limitation "said oronasal device" in line 8. There is insufficient antecedent basis for this limitation in the claim.

6. Dependent claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention. Claim 87 is now constructed as an apparatus claim which claims dependency to claim 85, which is a method claim. Therefore the claim is rendered vague and indefinite.

7. Dependent claim 93 recites the limitation "said prongs" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims dependent of claim 93 also recites the same limitation "prong".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5, 28, 32, 36-39, 41, 42, 44, 50, 55-57, 62-65, 80-83, 88-97, 103-109, 114-120, 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,422,240 to Levitsky et al. in view of US 6,439,234 to Curti et al.

10. As to claims 1-5, 28, 32, 36, 57, 58, 62, 63, 80-83, 93-97, 103, 104, 116-120, 126 and 127, Levitsky teaches a method of supplying gas to a person and sampling expired gas from the person, the method comprising: positioning an oral-nasal gas device **76** (Fig. 6A,6B) on the person in an area between a nose and a mouth of a person, the oronasal device having a lumen for supplying a gas from a source to the person (within tube **86**) and fluid outlets **88** that direct said supplied gas toward cannula nostrils of the nose and toward the mouth for inhalation, the device also having portions that extend

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from a body of the device, two of the portions **78** extending such that each may be inserted into a different nostril of the nose and a third portion **80** extending into a breath stream of the mouth, said two nostril portions having fluid inlets **78** adapted to channel expired gases from the nares to a sensor for detecting when the person is inhaling and exhaling, wherein the fluid outlets are located away from the fluid inlets to minimize mixing of expired gases and said supplied gas; collecting expired gases using the fluid inlets and analyzing the expired gas using an analyzer (col. 7, line 46); wherein the supplied gas is pure oxygen; wherein the analyzed expired gas is CO₂; wherein the device is a pneumatic harness and are capable of being separated along a line from each other (with excessive force); wherein the pneumatic harness can attach to a medical device (oxygen source); wherein the portions have a distal end and a proximate end, wherein the fluid outlets comprise a plurality of holes (embodiment shown in Fig. 8A,8B; prong **104** is porous) to diffuse the delivered gas; wherein the holes are concentric (inherent since the prong is entirely porous); wherein the fluid outlets are downstream from the fluid inlets.

Levitsky is silent with regards to the steps of determining whether the person is in inhalation or exhalation phase and delivering an increased flow of inspired gas to the person during the inhalation phase; wherein the supplied inspired gas is a gas mixture.

Curti also teaches a method of supplying gas to a person and sampling expired gas from the person, the method comprising the steps of using a nasal cannula to detect when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase (col. 3, lines 11-24). The incorporated US

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5,626,131 reference teaches a method of intermittent gas insufflation, which teaches detecting the respiratory phase of a user.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the method step of detecting when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase, as disclosed by Curti, in the method taught by Levitsky because delivering gas only during the inhalation phase prevents diluting the expired gas needed for sampling (Curti; col. 2, lines 38-52). Furthermore, it would have been obvious to supply a gas mixture to the person depending on the intended therapy and since it is well known in the art to supply air or vaporized medicaments to a person.

The combination of Levitsky/Curti teaches the determining step comprising monitoring changes in a sum of the pressure detected at the nares (via Curti, US 5,626,131, incorporated to US 6,439,234); wherein the delivering step is initiated when the an upper threshold is reached.

11. As to claims 37-39, 41, 42, 44, 50, 55, 56, 64, 65, 88-92, 105-109, 114, 115, Levitsky teaches an apparatus that delivers inspired gas to a person and samples expired gases from the person, the apparatus comprising: a lumen (within tube **86**) for providing gas from a delivery device (not shown in Fig. 6A,6B); a maskless oronasal oral-nasal device **76**, the mask having portions adapted to extend from the body, two of said portions **78** extend such that each may be inserted into a different nostril and a third portion **80** extending into the breath stream of the mouth, the oronasal device comprising a plurality of fluid outlets **88**; wherein said portions have inlet (the end of the

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portions **78, 80**) for collecting expired gases individually from each nostril and mouth area (each portion **78, 80** collect expired gases individually from each site prior to converging into a single line); an analyzer (col. 7, line 46) for detecting characteristics of the expired breath stream via a gas detecting device (capnograph); wherein a CO₂ sensor is used to measure the presence of CO₂; wherein the portions have at least one nasal portion for each of the nostril and at least one portion for the mouth, wherein said portions have distal ends with gas inlets at the distal ends, and wherein the gas inlets extend into expired breath airstreams of the nose and mouth; wherein the cannula is disposable and wherein the lumens can be torn downed along a line; wherein the lumen of the tube for inspired gases grid is larger than any other lumen (Fig. 7B); wherein the device is a pneumatic harness and the lumens are capable of being separated from each other along a line; wherein the pneumatic harness can attach to a medical device; wherein the prongs have a distal end and a proximate end, wherein the fluid outlets comprise a plurality of holes (prong **104** is porous) to diffuse the delivered gas; wherein the holes are concentric (inherent since the prong is entirely porous); wherein the fluid outlets are downstream from the fluid inlets.

Levitsky is silent with regards to a set of lumen for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase and an inspired gas delivery device comprising a mechanism for delivering variable flow of a gas to the person and a controller for managing the mechanism in response to the respiratory phase of the person.

Curti teaches an oxygen delivery device for supplying gas to a person and sampling expired gas from the person comprising a set of lumens for detecting when a person is inhaling and exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase and an inspired gas delivery device comprising a mechanism for delivering variable flow of a gas to the person and a controller for managing the mechanism in response to the respiratory phase of the person; wherein an increase flow of gas is delivered during the inhalation phase (col. 3, lines 11-24); wherein the analyzer comprises capnometers (col. 2, lines 32-33). The incorporated US 5,626,131 reference teaches a method of intermittent gas insufflation, which teaches detecting the respiratory phase of a user.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the oxygen delivery device of Curti with the nasal cannula of Levitsky because the delivery means of Curti prevents diluting the expired gas needed for sampling (Curti; col. 2, lines 38-52). Furthermore, it would have been obvious to supply a gas mixture to the person depending on the intended therapy and since it is well known in the art to supply air or vaporized medicaments to a person.

The combination of Levitsky/Curti teaches monitoring changes in a sum of the pressure detected at the nares (via Curti, US 5,626,131, incorporated to US 6,439,234); wherein the delivering step is initiated when the an upper threshold is reached.

12. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and in view of US 5,626,131 to Chua et al.

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Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a pressure sensor. Chua teaches an oxygen delivery system comprising a pressure sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Chua in the method steps taught by Levitsky/Curti because Curti teaches that the delivery system of Chua reduces the possibility of distorted carbon dioxide readings due to gas mixing (col. 3, lines 20-25).

13. Claims 21-26, 60, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and in view of US 6,467,477 to Frank et al.

Levitsky/Curti fails to teach the method of determining whether the person is inhaling and exhaling comprising the step of analyzing pressuring the person's gas stream using a humidity or temperature sensor. Frank teaches an oxygen delivery system comprising a humidity or temperature sensor for detecting whether the person is inhaling or exhaling and monitors the respiratory rate of the person at the respiratory site (col. 7, lines 19-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the delivery system of Frank in the method steps taught by Levitsky/Curti because it allows the person to control the delivery device using different sensors and different parameters.

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14. Claims 33-35 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al., and in further view of US 5,937,858 to Connell.

Levitsky/Curti fails to teach the method of analyzing the expired gases to monitor a level of an intravenous propofol anesthetic. Connell teaches a method of providing breathable air and sampling expired gases, wherein one of the expired gases is anesthetic gas (col. 2, lines 55-57), such as propofol (col. 1, line 45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Levitsky/Curti to analyze expired anesthetic level, because it would the practitioner to monitor the amount of anesthesia wasted into the atmosphere and to confirm that the patient is still currently receiving anesthesia.

15. Claims 36 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and Connell, and in further view of US 5,099,834 to Fishman.

The above combination, as recited in the rejections to claims 33-35, teaches all the limitations of the claim except for detecting xenon in the expired gas. However, Fishman teaches that xenon is used for anesthetizing a patient (col. 2, line 16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use and detect xenon in the expired gases of a patient because xenon is a well known anesthesia agent.

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16. Claims 46-49 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levitsky et al. in view of Curti et al. and in view of US 4,602,644 to DiBenedetto et al.

Levitsky/Curti fails to teach the apparatus comprising an auditory breath sonification device, wherein the device is a microphone; wherein the person's breathing sound is simulated to distinguish between the person's inhalation and exhalation phase. DiBenedetto teaches a nasal cannula having a microphone for amplifying a person's breathing pattern and determining a person's respiratory phase. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the microphone of DiBenedetto in the device of Levitsky/Curti because it allows a physician or caregiver to monitor the breathing of the person/patient.

Allowable Subject Matter

17. Claims 10-14, 27, 29-31, 40, 43, 45, 59, 84-86, 98-102, 110-113 and 121-125 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

18. Applicant's arguments filed 05/04/2005 have been fully considered but they are not persuasive.

In response to applicant's arguments that Levitsky fails to teach a cannula that collects gases individually, it is again noted that Levitsky teaches an oronasal cannula having a sampling inlet in each of the nostril and the mouth area. The claimed invention would only read over Levitsky if Levitsky merely teaches a single inlet port.

With regards to the motivation for combining the Levitsky and Curti references, it should be noted that both references teach a method and device for supplying gas and sampling expired gas. However, Curti teaches an additional step of detecting when a person is inhaling or exhaling and delivering an increase flow of gas to the person during the inhalation phase (col. 3, lines 11-24). Therefore, the motivation to combine the detection step of Curti to the method of Levitsky is to prevent the dilution of the expired gas needed for sampling (Curti; col. 2, lines 38-52). Though applicant contends that Levitsky discloses that Curti does not provide "collecting gases for a completely accurate analysis" it should be noted that the step of detecting inhalation through the expired gases is irrelevant of "complete accurate analysis". The examiner agrees that the cannula device of Levitsky and Curti are different but the method of using any sampled gas to determine the inhalation phase is irrelevant to the device so long as the device is capable of monitoring the expired gas.

The difference between the prior art and the applicant's invention is the method of detecting a respiratory site, i.e., whether the patient is inhaling via the nostrils or the mouth.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER